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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Docket Number (Optional)

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REISSUE APPLICATION DECLARATION BY THE INVENTOR

	56104576-111
As a below named inventor, I hereby declare that:  My residence, mailing address and citizenship are stated below next to my not I believe I am the original, first and sole inventor (if only one name is listed be joint inventor (if plural names are listed below) of the subject matter which is on patent number 6,402,913 B, granted 6/11/2002 relssue patent is sought on the invention entitled SEPARATION OF PLAS	elow) or an original, first and described and claimed for which a
the specification of which	
is attached hereto,	
was filed on as reissue application numb	per
and was amended on	
which application claims priority from Australian a filed on April 12, 1999.	application no. PP 9713,
I have reviewed and understand the contents of the above identified specifica amendment referred to above.  I acknowledge the duty to disclose information which is material to patentabili 37 CFR 1.56.  I verily believe the original patent to be wholly or partly inoperative or invalid, to below. (Check all boxes that apply.)	ty as defined in
by reason of a defective specification or drawing	

At least one error upon which reissue is based is described below. If the reissue is a broadening reissue, such must be stated with an explanation as to the nature of the broadening:

by reason of other errors.

by reason of the patentee claiming more or less than he had the right to claim in the patent.

Claims 1-20 are too narrow. Accordingly, this reissue is a broadening reissue. Claims 1-20 are too narrow in that claim 1 (from which claims 2-19 depend) recites only one specific embodiment of the methods described in the application. The specification clearly describes many alternatives and variations of the four step process recited in newly added claim 21.

For example, the specification clearly supports multiple apparatus being used in the methods as well as different buffer pH, and different solvent streams recovering the desired product. As another example, the specification also supports

(continued on page 3)

[Page 1 of 3.]

This collection of information is required by 37 CFR 1.175. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. B x 1450, Alexandria, VA 22313-1450.

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Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.  Docket Number (Optional)							
•	ION DECLARATION BY THE INVENTOR		_		56104576-111		
inventor, I hereby appo	this reissue application arose without an bint the following attorney(s) and/or agent and Trademark Office connected therewith	t(s) to pi	otive inten rosecute t	tion on the par his application a	of the ap and transa	oplicant. act all bu	As a named usiness in the
Name(s)	Registration Numb	er					
	cobs (Reg. No. 24,299); Eunl ro (Reg. No. 44,700)	nee Pa	rk (Re	g. No. 42.	976);		
Correspondence Addre	ess: Direct all communications about the	applicat	ion to:				
x Customer Nun	nber 26453		_		Customer N abel here	lumber B	iar 📗
	Type Customer Number h	ere			Abel Hele		
Firm or Individual Name	James David Jacobs, Esq.	c/o I	3aker &	McKenzie			
Address	805 Third Avenue Floor 29	9			-		
Address							
City	New York		State	NY		Zip	10022
Country	USA		<u></u>				
Tel phone	212-751-5700		Fax	212-759	-9133		
I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine and imprisonment, or both, under 18 U.S.C. 1001, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this declaration is directed.							
Full name of sole or fire Andrew Mark G11	st inventor (given name, family name)						
Inventor's signature	while little	Date	J-6	03			
	1-3 Helen Street,	Citizer	nship tralia				
Mailing Address	South Wales 2066, Australia	Aus	LLarra				
Full name of second to	oint inventor (given name, family name)						
Brendon Conlan	intiliventor (given name, same, same,	<del></del>			····		
Inventor's signature		Date					
Residence RMB 120, Binya, Citizenship							
New South Wales 2665, Australia Australia Australia Malling Address							
Full name of third joint inventor (given name, family name) Chenicheri Hariharan Nair							
Inventor's signature	an	Date	216-	L 07	,		
Residence 69 Delaney Drive, Baulkham Hills, Citizenship New South Wales 2153, Australia  Australia							
Mailing Address							
Additional joint inventors	s or legal representative(s) are named on separately	numbered	sheets form	ns PTO/SB/02A or 0	2LR attached	i hereto.	

PTC/SB/51 (05-03)
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| Docket Number (Optional)

(REISSUE APPLICAT	ION DECLARATION BY THE INVENTOR	R. page	2)				· (Optonal)	1
			,		56104	************		1
Inventor, I hereby appo	this reissue application arose without ar bint the following attorney(s) and/or agen and Trademark Office connected therewith	t(s) to p	ptive Intent rosecute th	tion on the par als application of	t of the ap and transa	pplican act all b	t. As a named ousiness in the	
Name(s)	Registration Numb	oer						
James David Jac	cobs (Reg. No. 24,299); Eunl	hee Pa	ark (Res	No. 42.	976):			1
Frank M. Gaspar	co (Reg. No. 44,700)				·····			
Correspondence Addre	ess: Direct all communications about the	applicat	ion to:	,	<del></del>			
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	Type Customer Number h	ere						
Firm or Individual Name	James David Jacobs, Esq.	c/o I	Baker &	McKenzie			***************************************	
Address	805 Third Avenue Floor 29	9						1
Address						,	······································	1
City	New York		State	NY		Zip	10022	
Country	USA	~						
Telephone	212-751-5700		Fax	212-759	-9133			
and belief are believe statements and the like false statements may declaration is directed.	all statements made herein of my own kneed to be true; and further that these as so made are punishable by fine and impleopardize the validity of the application inventor (given name, family name)	stateme prisonm	nts were i ent, or both	made with the n, under 18 U.S	knowled S.C. 1001,	ige tha , and th	it willful false nat such willful	
Andrew Mark G1							·····	
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Residence Unit 18 1-3 Helen Street, Citizenship								
Lane Cove, New South Wales 2066, Australia Australia						ą.		
Malling Address								
	int inventor (given name, family name)							
Brendon Conlan Inventor's signature		Date	<del></del>	<del></del>				
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Residence RME 120	, Binya,	Citizen	ship	······································	*****		<del></del>	***************************************
New South Wales 2665, Australia Australia								
Making Address								
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Inventor's algnature	***************************************	Date		·····	***************************************	**********	***************************************	
Resslers 69 Delansy Drive, Baulkham Hills Chrenship New South Wales 2153, Australia Australia Making Address								
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CII Additional joint invention or legal representative(v) are named on expansivy numbered sheets share PTO/SB/02A or 02LR effected frends.

(continued from page 1 of Reissue Declaration by the Inventor, form PTO/SB/51)

simultaneous as well as sequential separations. Because of the narrowness of scope, none of these embodiments are recited in claims 1-20.

In still another example, the specification also describes one embodiment of a simultaneous separation in which protein contaminants under 200 kDA are separated from immunoglobulins during the separation of albumin /alpha 1-antitrypsin from the plasma sample. These contaminants having a molecular weight less than immunoglobulins are removed from a first stream to a second stream and remain with the albumin/alpha-1-antitrypsin fraction. Yet, claim 1 and its dependents require that contaminants having a molecular weight less than immunoglobulins be separated from the albumin/alpha-1-antitrypsin fraction in step (c). 1, the contaminants with lower molecular weights than immunoglobulins are not separated from the immunoglobulin fraction until step (h), in which these contaminants are removed from a third solvent stream into a fourth solvent stream. essence, claim 1 and its dependents require that the contaminants having a lower molecular weight than immunoglobulins be separated from the albumin/alpha-1-antitrypsin fraction and these contaminants reside with the immunoglobulin fraction before being By contrast, the simultaneous separation discloses separated. that the contaminants having a lower molecular weight than immunoglobulins are separated from the immunoglobulins and reside with the albumin/alpha-1-antitrypsin fraction before being separated. This method of separating components from plasma is not recited in claims 1-20.

In error, the scope of claims 1-20 are too narrow because many of the variations and alternatives supported by the specification are not recited in the present claims.

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## REISSUE APPLICATION DECLARATION BY THE INVENTOR

Docket Number (Optional)

5610/576-111

	50104370-111
My re i belie joint i in pat	below named inventor, I hereby declare that: esidence, mailing address and citizenship are stated below next to my name. eve I am the original, first and sole inventor (if only one name is listed below) or an original, first and inventor (if plural names are listed below) of the subject matter which is described and claimed tent number 6,402,913 B , granted 6/11/2002 for which a ue patent is sought on the invention entitled SEPARATION OF PLASMA COMPONENTS,
the sp	pecification of which
[X	is attached hereto,
	was filed on as reissue application number
	and was amended on
fil.	ch application claims priority from Australian application no. PP 9713, ed on April 12, 1999.
amen I ackn 37 CF I verily	e reviewed and understand the contents of the above identified specification, including the claims, as amended by any dment referred to above.  nowledge the duty to disclose information which is material to patentability as defined in FR 1.56.  by believe the original patent to be wholly or partly inoperative or invalid, for the reasons described
below	. (Check all boxes that apply.)
	by reason of a defective specification or drawing.
<b>x</b>	by reason of the patentee claiming more or less than he had the right to claim in the patent.
	by reason of other errors.
At lea: reissu	st one error upon which reissue is based is described below. If the reissue is a broadening e, such must be stated with an explanation as to the nature of the broadening:
reci The step	Claims 1-20 are too narrow. Accordingly, this reissue is a broadening reissue. Ims 1-20 are too narrow in that claim 1 (from which claims 2-19 depend) ites only one specific embodiment of the methods described in the application. specification clearly describes many alternatives and variations of the four process recited in newly added claim 21. For example, the specification clearly supports multiple apparatus being used the methods as well as different buffer pH, and different solvent streams overing the desired product. As another example, the specification also supports
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of Information unless it displays a valid OMB control number. Docket Number (Optional) (REISSUE APPLICATION DECLARATION BY THE INVENTOR, page 2) 56104576-111 All errors corrected in this reissue application arose without any deceptive intention on the part of the applicant. As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the United States Patent and Trademark Office connected therewith. **Registration Number** James David Jacobs (Reg. No. 24,299); Eunhee Park (Reg. No. 42,976); Frank M. Gasparo (Reg. No. 44,700) Correspondence Address: Direct all communications about the application to: X Customer Number 26453 Place Customer Number Bar Code Label here Type Customer Number here x Firm or James David Jacobs, Esq. c/o Baker & McKenzie Individual Name Address 805 Third Avenue Floor 29 Address City State New York 10022 NY Country USA T lephone Fax 212-751-5700 212-759-9133 I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine and imprisonment, or both, under 18 U.S.C. 1001, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this declaration is directed. Full name of sole or first inventor (given name, family name) Andrew Mark Gilbert inventor's signature () 5-6-03 Date Residence Unit 18 1-3 Helen Street, Citizenship Lane Cove, New South Wales 2066, Australia Australia **Mailing Address** Full name of second joint inventor (given name, family name) Brendon\_Conlan Inventor's signature Date Residence RMB 120, Binya, Citizenship New South Wales 2665, Australia Australia Mailing Address Full name of third joint inventor (given name, family name) Chenicheri Hariharan Nair Inventor's signature Date Residence 69 Delaney Drive, Baulkham fiils New South Wales 2153, Australia Citizenship Australia Mailing Address

Additional joint inventors or legal representative(s) are named on separately numbered sheets forms PTO/SB/02A or 02LR attached hereto.

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Name(s) Registration Number						
James David Ja	cobs (Reg. No. 24,299); Eun	hee Park (Reg. No. 42,	976);			
Frank M. Gaspa	ro (Reg. No. 44,700)					
Correspondence Addr	ess: Direct all communications about the	application to:				
X Customer Number						
	Type Customer Number h	16/6 <u></u>				
y First of Individual Name	James David Jacobs, Esq.	c/o Baker & McKenzie				
Address	805 Third Avenue Floor 2	9				
Address						
City	Nes York	State NY	<sup>Z©</sup> 10022			
Country USA						
Telephone	212-751-5700	Fax 212-759	-9133			
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Andrew Mark Gi Inventor's signature	alan liller	Date 3 - (				
	1-3 Helen Street,	Citizenship				
Lane Cove, New South Wales 2066, Australia Australia Malling Address						
Full name of second ic	oint inventor (given name, family name)			1		
Brendon Conlan		· · · · · · · · · · · · · · · · · · ·				
Inventor's signature	S. Con-	Date 29/6/03				
Residence RMB 120		Citizenship				
New South Wales 2665, Australia Australia						
Mailing Address						
Full name of third joint inventor (given name, family name) Chen Loher L. Har Thuran Natr						
Inventor's signature		Date				
Residence 69 Delaney Drive, Baulkham Hills, Chizenship Naw South Wales 2151; Australia Australia Malling Address						
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[Page 1 of 3]

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Name(s)	Registration Number	er						
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	o (Reg. No. 44,700)					<del></del>	<del></del>	
Correspondence Addre	ess: Direct all communications about the	applicat	ion to:					
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	Type Customer Number he	ere		L		~~~~		
Firm or Individual Name	James David Jacobs, Esq.	e/o E	laker &	McKenzie		~~~~		
Address	805 Third Avenue Floor 29	}						
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City	New York		State	KY		Ζiφ	10022	
Country	USA			······································	<del></del>		·····	
Telephone	212-751-5700		Fax	212-759	**********			
and belief are believe statements and the like false statements may declaration is directed.	ill statements made herein of my own kr ed to be true; and further that these a so made are punishable by fine and impleopardize the validity of the application of inventor (given name, family name)	statente: orisona:	nts were ani, or bot	made with the h, under 18 U.S	: knowled S.C. 1001,	ge tha and th	t willful false at such willful	
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inventor's signature	while with the terms of	Date	<u> </u>	603			4	
Residence Unit 18 1-3 Helen Street, Cazenship Lane Cove, New South Wales 2066, Australia Australia								
Mailing Address	BRILLI WALES LVOV, RUSCIBLIA	35(1:5)	C10222	***************************************	******	······································	<del>*************************************</del>	7
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Brendon Conlan Inventors signature	20 -	Date	29/6	/03	·····			/
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Residence RMB 120, Binya, Chizenship New South Weles 2665, Australia Australia								
Mailing Address								
Full name of third joint Chenicheri Bar:	inventor (given name, family name) Iharan Nair				***************************************		***************************************	B0000000000000000000000000000000000000
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Residence 69 Delaney Drive, Baulkham Hills, Chizenship New South Wales 2153, Australia Australia Mailing Address								
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(continued from page 1 of Reissue Declaration by the Inventor, form PTO/SB/51)

simultaneous as well as sequential separations. Because of the narrowness of scope, none of these embodiments are recited in claims 1-20.

In still another example, the specification also describes one embodiment of a simultaneous separation in which protein contaminants under 200 kDA are separated from immunoglobulins during the separation of albumin /alpha 1-antitrypsin from the plasma sample. These contaminants having a molecular weight less than immunoglobulins are removed from a first stream to a second stream and remain with the albumin/alpha-1-antitrypsin fraction. Yet, claim 1 and its dependents require that contaminants having a molecular weight less than immunoglobulins be separated from the albumin/alpha-1-antitrypsin fraction in step (c). In claim 1, the contaminants with lower molecular weights than immunoglobulins are not separated from the immunoglobulin fraction until step (h), in which these contaminants are removed from a third solvent stream into a fourth solvent stream. essence, claim 1 and its dependents require that the contaminants having a lower molecular weight than immunoglobulins be separated from the albumin/alpha-1-antitrypsin fraction and these contaminants reside with the immunoglobulin fraction before being By contrast, the simultaneous separation discloses that the contaminants having a lower molecular weight than immunoglobulins are separated from the immunoglobulins and reside with the albumin/alpha-1-antitrypsin fraction before being separated. This method of separating components from plasma is not recited in claims 1-20.

In error, the scope of claims 1-20 are too narrow because many of the variations and alternatives supported by the specification are not recited in the present claims.

Approved for use through 01/31/2004. OMB 0651-0033 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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REISSUE APPLICATION: CONSENT OF ASSIGNEE; STATEMENT OF NON-ASSIGNMENT	56104576-111					
This is part of the application for a reissue patent based on the original patent identified below.  Name of Patentee(s)  Andrew Mark Gilbert, Brendon Conlan, Chenicheri Hariharan Nair						
Patent Number Date Patent Issued 6/11/2002						
Title of Invention SEPARATION OF PLASMA COMPONENTS						
1. X Filed herein is a statement under 37 CFR 3.73(b). (F	Form PTO/SB/96)					
2. Ownership of the patent is in the inventor(s), and no	2. Ownership of the patent is in the inventor(s), and no assignment of the patent is in effect.					
	One of boxes 1 or 2 above must be checked. If multiple assignees, complete this form for each assignee. If box 2 is checked, skip the next entry and go directly to "Name of Assignee".					
The written consent of all assignees and inventors owning an undivided interest in the original patent is included in this application for reissue.						
The assignee(s) owning an undivided interest in said original patent is/are <u>Gradipore Limited</u> , and the assignee(s) consents to the accompanying application for reissue.						
Name of assignee/inventor (if not assigned)						
Gradipore Limited						
Signature ( )	Date 3 Sune 2003					
Typed or printed name and title of person signing for assignee (if ass	signed)					
Tim LAWN						
CHIEF OPERATING OFFICER						

This collection of information is required by 37 CFR 1.172. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 6 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: C mmissi n rf r Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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STATEMENT UNDE	R 37 CFR 3.73(b)
Applicant/Patent Owner: Gradipore Limited	ARV
Application No./Patent No.: 6,402,913 B1	Filed/Issue Date:6/11/2002
Entitled: SEPARATION OF PLASMA COMPONENT	S
Gradipore Limited ,an Austr	alian corporation,
(Name of Assignee) (Type of Assi	gnee, e.g., corporation, partnership, university, government agency, etc.)
states that it is:	
1. 🖼 the assignee of the entire right, title, and interest;	nr.
2. an assignee of less than the entire right, title and i	
The extent (by, percentage) of its ownership intere	st is%
in the patent application/patent identified above by virtue	of either:
A. [x] An assignment from the inventor(s) of the patent a was recorded in the United States Patent and Trac which a copy thereof is attached.	pplication/patent identified above. The assignment demark Office at Reel <u>Q1100</u> 8=rame <u>0897</u> , or for
OR	
B. [ ] A chain of title from the inventor(s), of the patent a assignee as shown below:	
1. From:To	·
The document was recorded in the United St Reel, Frame	ates Patent and Trademark Office at
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[ ] Additional documents in the chain of title are	listed on a supplemental sheet.
[ ] Copies of assignments or other documents in the chair [NOTE: A separate copy (i.e., the original assignment must be submitted to Assignment Division in accordan recorded in the records of the USPTO. See MPEP 302	document or a true copy of the original document) ce with 37 CFR Part 3, if the assignment is to be .08]
The undersigned (whose title is supplied below) is authoriz	ed to act on behalf of the assignee.
3 JUNE 2003	TIM WANN
Date	Typed or printed name
_	Signature
	CHIEF OPERATING OFFICER
	Title